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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,680	01/24/2001	Asger Geppel	54337.000010	4425

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/767,680

Applicant(s)

GEPPEL ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-17, 29-56 and 58-61 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 and 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-17, 35-47 and 58-61 is/are rejected.
- 7) ☒ Claim(s) 34, 48-52 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 20060807.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 4-17, 29-56 and 58-61 are pending.

Applicants' amendment filed August 8, 2006 is acknowledged. Applicants' response has been fully considered. Claims 4-17, 34-52 and 56 have been amended, and new claims 58-61 have been added. Claims 29-33 and 53-55 are non-elected invention and withdrawn from consideration. Therefore, claims 4-17, 34-52, 56 and 58-61 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 4-17, 34-52 and 56, under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 11-16 in the amendment filed August 8, 2006.
3. The previous rejection of claims 5, 12, 16, 40-42 or 48-52, under 35 U.S.C. 112, first paragraph, scope of enablement or enablement, is withdrawn in view of applicants' amendment of the claim, and applicants' response at page 16 in the amendment filed August 8, 2006.

Withdrawn Claim Rejections - 35 USC § 103(a)

4. The previous rejection of claims 48 and 49, under 35 U.S.C. §103(a) as being unpatentable over Kaneko et al. (USPN 5,075,226), is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 17-18 in the amendment filed August 8, 2006.

Maintained - Claim Rejections - 35 USC § 112, first paragraph

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5. Previous rejection of Claims 8-9 under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement is maintained (see paragraph 24 of the Office Action dated 8/1/03, and paragraph 13 of the Office Action dated 11/19/2004). To make the cells claimed that will be effective when inoculated in a concentration of 10^7 cells/ml into low pasteurized skimmed milk having 8 ppm of dissolved oxygen would require undue experimentation. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

6. Previous rejection of Claim 9 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained (see paragraph 24 of the Office Action dated 8/1/03, and paragraph 14 of the Office Action dated 11/19/2004), because the specification, while being enabling for lactic acid bacterial cells modified to consume at least 50% of dissolved oxygen with treatment under aerobic conditions, does not reasonably provide enablement for lactic acid bacterial cells modified when fermented under anaerobic conditions. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

7. Previous rejection of Claims 45-47 under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement is maintained (see paragraph 30 of the Office Action dated 8/1/03, and paragraph 18 of the Office Action dated 11/19/2004). The claims

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contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention at "at least 40 ppm" or higher of a cytochrome. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-42 are indefinite because claims 40-42 have the same scope as claim 13.

Maintained - Claim Rejections - 35 USC § 103(a)

9. Previous rejection of Claims 4-7, 10-17, 35-39, 43 and 44 under 35 U.S.C. § 103(a) as being unpatentable over Kaneko *et al.* (USPN 5,075,226) is maintained (see paragraph 19 of the Office Action dated 11/19/2004), and new claims 58-61 have been added to the rejection. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the claims have been amended to an isolated starter culture useful in manufacturing and preservation of food and feed products comprising at least one modified

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lactic acid bacterial cell. There is no teaching in Kaneko et al, nor a suggestion to modify the teachings of Kaneko et al, to obtain the claimed isolated starter culture. A “starter” culture has a defined or recognized meaning in the art (see the definition in McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Ed., Appendix C). The bacterial cultures as described by Kaneko *et al.* are used to produce diacetyl and acetoin, where the culture solution produced is used to improve the flavor of food, and there is no discussion or contemplation of the isolation or harvesting of these bacteria from the end products following completion of the fermentation process for any use, much less as an isolated starter culture (see Examples 1-5). Additionally, the concentration of haemin used by Kaneko et al. differs significantly from the concentration used in Applicants' invention. Kaneko et al. teaches two examples of using haemin in a starter, Example 1 using 5 μM , Example 5 using 1 μM , and a comparative example using 300 $\mu\text{g}/100$ mL of haemin (corresponding to 4.6 μM). Kaneko et al. only includes prophetic discussion of using haemin in a range of 0.1 to 500 μM with a preferred embodiment of 0.5 to 5 μM of haemin. In contrast, the instant application uses 10 mg/L haemin which is 15 μM , at least three times the amount exemplified by Kaneko et al. The reference does not contain any teaching, motivation, or suggestion to increase the amount of haemin from 5 μM to 15 μM . Kaneko et al. do not teach an isolated starter culture, nor does present any evidence that the cultures produced by their method have at least one modified lactic acid bacterial cell comprising at least 0.1 ppm on a dry matter basis of a porphyrin compound which includes iron. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §103(a) (pages 14-15 of the response).

Applicants' response has been fully considered, however the arguments are not found persuasive because of the following reasons. Kaneko *et al.* teach culturing lactic acid bacteria, aerobically, in haemin (MW 651 g/mol) at a concentration of 0.1-500 μM (column 3, lines 21-24; Examples; where 0.1-500 μM corresponds to 0.065 to 327 mg/L haemin), and using concentration of 1-2% in inoculation as a starter culture to produce diacetyl and acetoin (see column 5; Example 1). Since culturing lactic acid bacteria in a medium containing 10 mg/L haemin produces a modified lactic acid bacterial cell comprising at least 0.1 ppm of haemin as evidenced by Geppel et al. (US 2001/0033879 A1), and Kaneko *et al.* teach culturing lactic acid bacteria in haemin (e.g., at a concentration of 500 μM), it would be expected that Kaneko *et al.* teach a culture solution having a modified lactic acid bacterial cell comprises at least 0.1 ppm of haemin as the claimed invention. Furthermore, the culture solution of Kaneko *et al.* is used to increase or improve the flavor of foods (column 5, lines 6-10), it would be expected that the culture solution would be isolated for subsequent use. Moreover, the term cited in the claim "useful in manufacturing and preservation of food and feed products" is an intended use, which does not have weight in a product claim. Although the Examples of Kaneko *et al.* indicate culturing lactic acid bacteria in haemin at a concentration of 1 or 5 μM , the reference does suggest the use of porphyrin compound up to 500 μM (which corresponds to 327 mg/L haemin) in culturing lactic acid bacteria. Thus, it would be obvious that the culture solution of Kaneko *et al.* results in the claimed starter culture. Therefore, the rejection of the claims under 35 U.S.C. §103(a) is maintained.

Claim Objections

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10. Claims 34, 48-52 and 58-61 are objected to because the claims are dependent from a rejected claim.

Conclusion

11. Claims 4-17, 35-47 and 58-61 are rejected; and claims 34, 48-52 and 56 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

October 24, 2006